K081324

CANDELA

510(k) Summary

JUN 17 2008

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92.

Submitter Information

Company Name:	Candela Corporation
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Contact Person:	Lisa LaCroix Senior Regulatory Affairs Specialist
Date summary Prepared:	May 9, 2008

Device Identification

Device Trade/Proprietary Name:	The Candela Family of Q-Switched Alexandrite Lasers
Common Name:	Q-Switched Alexandrite Laser
Classification Name:	Laser Surgical Instrument, for use in General and Plastic Surgery and Dermatology
Classification Regulation:	21 CFR § 878.4810
Device Classification:	II

Identification of Predicate Device

Predicate Device(s):	Candela Q-Switched Alexandrite Laser, K073534 Candela 3630 Laser System (Alexandrite) K063074 Cynosure Accolade Elite Laser (Alexandrite) K072868

Device Description

The Candela Q-Switched Alexandrite Laser consists of an Alexandrite laser head, power supply and deionized water circulator The laser head contains cavity mirrors, pockels cell, solid state laser medium (the Alexandrite rod), and two high intensity xenon flashlamps which excite the laser medium. A calibration port with an internal meter is located on the control panel, which is used to verify the transmission of the optical fiber and handpiece, and to calibrate the output of the handpiece at selected fluence levels. The temperature of the laser head is regulated by the circulation of distilled water at a controlled temperature.

The Candela Q-Switched Alexandrite Laser delivers laser energy at a wavelength of 755 nm and pulse duration between 50 and 120 microseconds. When the Q-switching mechanism is disabled the system has the capability of producing a laser pulse duration of 0.050 – 0.120 milliseconds. The output of this laser is delivered to the area of treatment by means of a lens coupled user replaceable optical fiber with a treatment

handpiece attached to its distal end. A trigger switch is used to control the delivery of pulses.

A microprocessor based system controller is used to monitor and direct all system functions. Users of the laser select parameters such as desired energy density (fluence) level and repetition rate and monitor operation via electronic controls and a display panel. The control panel is also used to enable or disable the triggering of the laser, to initiate the calibration feature and to obtain feedback from the system, such as the number of pulses delivered or spot size selected. The Candela Q-Switched Alexandrite Laser supports 2mm, 3mm, and 5mm nominal spot sizes.

Description of Intended Use
The Candela Family of Q-Switched Alexandrite Lasers are indicated for treatment in the following uses:

Pigmented Lesions
Tattoos

Rationale for Substantial Equivalence

The Candela Q-Switched Alexandrite Laser has the same intended use, utilizes similar functional features (including power output, spot size, repetition rate, energy, and fluence) and matches key design aspects (including wavelength, light generation medium, power supply, cooling and controls system) , as the predicate devices.

The Candela Q-Switched Alexandrite Laser shares similar methods of assembly, method of operation, and intended uses, and therefore is substantially equivalent to the current legally marketed Candela Q-Switched Alexandrite Laser K073534, Candela 3630 Laser Systems, Alexandrite, K063074 and Cynosure Apogee Elite Laser, Alexandrite, K034030 predicate devices.

Safety and Effectiveness Information

Candela believes that there are no new questions of safety or effectiveness raised and the Candela Q-Switched Alexandrite Laser is substantially equivalent to the current legally marketed Candela Q-Switched Alexandrite Laser, K073534, Candela 3630 Laser System (Alexandrite) K063074, and Cynosure Apogee Elite Laser (Alexandrite) K034030 predicate devices in intended use and technological features and therefore the risks and benefits are comparable to the predicate devices.

Conclusion

Based on the similarities in indications for use, design features, and functional features, the Candela Q-Switched Alexandrite Laser has been shown to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Candela Corporation
% Ms. Lisa LaCroix
Senior Regulatory Affairs
Specialist
530 Boston Post Road
Wayland, Massachusetts 01778

JUN 17 2008

Re: K081324
Trade/Device Name: Candela Q-Switched Alexandrite Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 9, 2008
Received: June 10, 2008

Dear Ms. LaCroix:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device.on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Candela Q-Switched Alexandrite Laser

Indications for Use:

The Candela Q-Switched Alexandrite Laser is indicated for the following uses:

Pigmented Lesions
Tattoos

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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